K130374
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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
August 25, 2013

AUG 29 2013

Submitter's Information: 21 CFR 807.92(a)(1)
Mr. Alain Tabares, Chief Technical Officer
Genesis Digital Imaging, Inc.
12921 W. Washington Blvd.
Los Angeles, CA 90066

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	Omni-Vue 2™ System
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological[20]
510(K) Number	K073062
Device Name	OMNI-VUE SYSTEM
Applicant	GENESIS DIGITAL IMAGING, INC.
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	10/30/2007
Decision Date	03/10/2008
Decision	substantially equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Type	Traditional

Device Description: 21 CFR 807 92(a)(4)

Omni-Vue 2™ System makes possible the capturing, storage, distribution, manipulation, and networking of medical images at distributed locations. In cases where DICOM images are not directly available, the System can acquire medical images using a DICOM gateway, which generates DICOM-type files. For example, film digitizers obtain images from old film and convert them to meet DICOM standards and stored. Stored files are transmitted using a network and can be viewed or manipulated from an imaging workstation.

Indications for Use: 21 CFR 807 92(a)(5)

Omni-Vue 2™ System is a software device that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Device options make possible reading (including mammography), telecommunications; fast demonstration; etc.; and teleconferencing. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic

images may only be interpreted using an FDA cleared monitor that meets technical specifications reviewed and accepted by FDA.

Technological Characteristics: 21 CFR 807 92(a)(6)

Omni-Vue 2™ System is a software product that handles and manipulates digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed. OmniVue 2 is downsized product of OmniVue related with number of feature, however, OmniVue 2 improves data transfer security, and productivity and brevity of PACS configuration. The reason for data transfer security is improved, is due to FTPS(File Transfer Protocol SSL) and ODBC(Open Database Connectivity) on SSL. Another reason for brevity of PACS configuration is improved, is due to the fact that OmniVue 2 client application provides simple way to get image from CR, DR and digitizer.

The modified device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The 2 devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use.

Any difference between the two devices does not affect safety or efficacy. The predicate device and the new device are compared below:

Item	OmniVue 2	OmniVue Predicate	Description
Login	Yes	Yes	For security purpose, login function is recommended.
Patient's list	Yes	Yes	Easy way to find the patient
DICOM Storage SCU	Yes	Yes	Routing to another workstation
DICOM Storage SCP	Yes	Yes	Getting images from other workstation
DICOM Q/R SCU	Yes	Yes	Requests patient from PACS server.
DICOM Q/R SCP	Yes	Yes	Response for patient exam request. Neo module has this function.
DICOM Print Management	No	Yes	Film printing feature has been removed from the modified device. Difference between the predicate and modified device, but has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Open DICOM Dir CD	No	Yes	The feature to open patient's CD from other PACS devices has been removed from the modified device. Difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Burn patient's CD	Yes	Yes	
CR interface: Direct importing	Yes	Yes	CR: Carestream Vita interface
Film digitizer interface	Yes	Yes	Vidar film digitizer interface
Multi film scanning	Yes	Yes	Multi films at one time.
Manual image import	Yes	Yes	Importing image one by one.
Batch import	Yes	Yes	Importing multiple images in a certain folder.
Non-DICOM file open and import	No	Yes	The feature to open and import a non-DICOM file such as bmp, jpg and tiff and convert into DICOM format has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Paper printing	No	Yes	The feature to print a DICOM image to a paper printer has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety

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Item	OmniVue 2	OmniVue Predicate	Description
			risks
Twain interface	No	Yes	The Interface with twain device feature used to scan images and other items has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Auto close	No	Yes	The auto feature to close current exam whenever a new exam is opened has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Chest CT View	No	Yes	The feature to compare images at the same time with difference Window Width/Level has been removed in the modified device. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Image layout change	Yes	Yes	Change layout by user's demand.
Series layout change	Yes	Yes	Change series layout by user's demand.
Image manipulation tools - W/L - Rotation - Flipping - Zoom in/out - Magnify glass - Auto W/L - Reset modification - Invert	Yes	Yes	Basic tools to manipulate images
DICOM header view	Yes	Yes	DICOM header dump for administrator
Cine view	No	Yes	The feature for Cine View for a slide show for images has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.
Hounsfield unit	No	Yes	The feature for using CT exam Hounsfield unit has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Scout line	No	Yes	The scout line feature for CT and MR has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Close and Open	Yes	Yes	Close current exam open next exam
W/L preset	No	Yes	The Window/Level preset database feature has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Sharpen preset	No	Yes	The sharpen preset database has feature been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Look-Up Table preset	Yes	Yes	Use gamma value for image processing
Hanging protocol	No	Yes	The limited hanging protocol feature has been removed. The has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Hanging protocol preset	No	Yes	The preset for layouts feature has been removed from modified device. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks

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Item	OmniVue 2	OmniVue Predicate	Description
Thumbnail view	Yes	Yes	Thumbnail image for exam
Chiropractic tools - Cobb's angle - Center mass - Atlas plane line - New Cobb's angle - Extended Cobb's angle - Horizontal deflection - Chiro ratio - Measure from horizontal line	No	Yes	Specially designed tools for chiropractors has been removed from modified device. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
Arbitrary rotation	No	Yes	The rotate image with arbitrary angle feature has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
W/L for ROI only	No	Yes	The Window/Level feature in the ROI (region of interest) only has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks
ROI	Yes	Yes	Region of Interest (ROI)
Measuring tools - Ruler - Angle	Yes	Yes	Measure angle or length
Customizing DICOM overlay	No	Yes	The feature to insert a customized DICOM overlay on t he image has been removed. The difference t has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.
External program interface	Yes	Yes	Launch external program
Customizing toolbar set	No	Yes	The feature to customize toolbar icons has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.
Customizing worklist layout	Yes	Yes	Worklist layout change and column order change
Email with attachment	No	Yes	The feature to email an image file has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.
Old exam list	Yes	Yes	List up old exam for the patient
Reporting	Yes	Yes	Create diagnostic report by radiologist
L/R mark on image	No	Yes	The feature to mark left/right image is removed because the function resides in a different module that indicates L/R Mark on Image. This feature was a duplicate. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.
Masking	No	Yes	The feature to mask image pixel if the pixel value is same with certain color has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.
Image stitching	No	Yes	The feature to stitch multiple images to one has been removed The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.
Annotation	Yes	Yes	Write text on the image
All series mode	Yes	Yes	Set multiple series as one series

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Item	OmniVue 2	OmniVue Predicate	Description
DICOM information edit	Yes	Yes	Other module has it. Only technician can modify DICOM information when they made mistake.
Arrow lines	Yes	Yes	Draw arrow lines
Overlay show/hide	Yes	Yes	
Display original size image	No	Yes	The feature to display the image by real body size has been removed. The difference has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks.

Nonclinical Testing:

The complete system configuration has been assessed and tested at the factory and has passed all in-house testing criteria. The Verification & Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the Omni-Vue 2™ software in each operational mode and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

If the device is installed Genesis Digital Imaging, Inc., integration and installations verification tests are conducted against acceptance criteria prior to release to the client.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for Omni-Vue 2™ contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The modification to the subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, Omni-Vue 2™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

Genesis Digital Imaging, Inc.
% Mr. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K130374
Trade/Device Name: Omni-Vue 2™ System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 1, 2013
Received: August 13, 2013

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

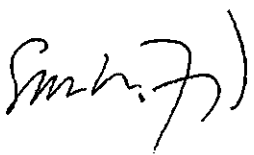
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130374

Device Name: Omni-Vue 2™

Indications for Use:

Omni-Vue 2™ System is a software device that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Device options make possible reading (including mammography), telecommunications; fast demonstration; etc.; and teleconferencing.
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor that meets technical specifications reviewed and accepted by FDA

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ____K130374_____